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Research Article

**FREQUENCY OF PRE-ANALYTICAL PHASE ERRORS IN A
CLINICAL CHEMISTRY LABORATORY**¹Dr Muhammad Zubair, ²Dr Ahmed Raza, ³Dr Tahir Mahmood¹PGR, Department of Chemical Pathology Chughtai Lab Lahore, ²Quaide Azam Medical College Bahawalpur, ³Demonstrator Physiology at Sahara Medical College Narowal.**Article Received:** March 2019**Accepted:** April 2019**Published:** May 2019**Abstract:*****Objective:** To find out the leading cause of pre analytical error in a clinical chemistry laboratory.****Duration and place:** This study was conducted in clinical chemistry laboratory at Chughtai Lab Lahore over a period of 1 year from January 2018 to December 2018.****Method:** It was a retrospective study which had been carried out to find out the frequency of various factors affecting the preanalytical phase of total laboratory testing. Data were gathered by the help of laboratory technologist who were register data of rejections, and causes for rejections of all the samples which were sent to clinical chemistry laboratory for analysis.****Results:** Of the 518765 tubes received during the data collection period, 1792 samples were found unsuitable for further processing. This accounted for 0.34% of all samples collected in the laboratory. Rejections arose as a result of the following reasons: 1256(0.24%) specimens had hemolysis ; 147(0.03%) had insufficient sample quantity, 389(0.07%) had compromised or unsatisfactory results.****Conclusion:** Of all the samples received in the lab, the overall percentage of rejection is 0.34%.***Corresponding author:****Dr. Muhammad Zubair,**

PGR, Department of Chemical Pathology Chughtai Lab Lahore.

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INTRODUCTION:

Laboratory medicine quality can be defined as the provision of confirmation that the report which is delivered to patient or clinician is accurate and reliable and which is helpful for the making of clinical decision and effective patient care [1]. The generation of any laboratory test involves various important steps like, Ordering of test from physician, specimen collection, identification, transportation, separation or preparation, analysis, reporting and provision of results. The errors in these various steps of lab testing constitute the total laboratory errors which can be further divided into three components: pre analytical, analytical, post analytical [2]. Pre analytical errors are those errors which occur before the analysis of the specimen and account for 65- 70% total laboratory errors. The most commonly reported types of pre-analytical error are: a) wrong or missing identification, b) haemolysed, clotted, and insufficient samples, c) inappropriate containers, f) inappropriate blood to anticoagulant ratio, and g) inappropriate transport and storage condition [3,4].

Analytical errors are those errors which occur during the analysis of the specimens on the analyzer and account for 15 to 20 % laboratory error. There is a great reduction in these errors over a couple of years due to standardization of analytic techniques, increase stability of reagents, advance instrumentation, innovation in information technology, quality control and quality assurance methods.

Post analytical phase errors are those errors which are caused by interruption in result transmission from analyser to laboratory information system, transcription related errors, incorrect interpretation. Total quality management program monitor and evaluate the ongoing and overall quality of total testing

process and the effectiveness of its policies and procedures. Quality assurance is a component of total quality management and deal with all the three phase of laboratory testing pre analytical, analytical and post analytical.

The rationale of this study was to enumerate and analyze the frequency of different preanalytical errors that occur during sample processing in the clinical chemistry and immunology laboratory so that we can improve those areas which leads to sample rejection in our laboratory set up.

MATERIAL AND METHOD:

The study was conducted in the department of clinical chemistry and immunology of chughtai institute of pathology from January 2018 to December 2018. The clinical chemistry department equipped with state of the art equipment like, Architect CI 8200, Alinity CI, Liasion XL, immulite XPr 2000, Helios, Blue dot driver, Alegria, cobas e411.

The data collection procedure involved review of blood samples received from the main head office reception as well as from collection points of laboratory situated at various cities. Venous blood samples are considered unsuitable according to the following accepted criteria: quantity not sufficient, wrong or missing patient identification, inappropriate specimen container, visible hemolysis after centrifugation, lipemic or turbid samples.

RESULTS:

A total of 518765 specimens were received over the course of one year in department of clinical chemistry and immunology from head office reception as well as from various collection points of the laboratory which are situated at various cities of Pakistan.

Frequency of various pre analytical errors

Total number of specimens	518765
Total number of samples rejected	1792(0.34%)
Total number of samples Hemolyzed	1256(0.24%)
Total number of samples Quantity not sufficient	147(0.03%)
Total number of samples Compromised or unsatisfactory results(wrong container, EDTA contamination, inappropriate time for sampling	389(0.07%)

A total of 1792 specimens had been rejected on the basis of our specimen rejection criteria. Most common cause of specimen rejection was hemolyzed specimen which account rejection of 1256 specimen over a period of one year. Secondly the specimen which were rejected were those which have wrong container

, EDTA contamination, turbidity of specimen, inappropriate time of sampling and account for rejection of 389 specimens. Only 147 specimens were rejected on the basis of insufficiency of sample volume in our laboratory. Percentage of all errors in table 1:

DISCUSSION:

During the last few decades, laboratory medicine had been revolutionized by transformation of laboratory diagnostics from manual, cumbersome testing methods to fully automated science, ensuring accuracy and speedy analysis. However, the laboratory cannot function in isolation. It is dependent upon other departments, mainly the clinical division for properly filled requisition slips and samples for analysis. Evidence indicate that accuracy and reliability in test can not achieved by only improving the analytical phase but The phases before the sample reaches the laboratory (preanalytical) and the phase after the sample is analyzed (post-analytical) are equally important. The pre analytical phase is accompanied by many short comings ranging from contamination of specimens due to non following the proper order of draw and lack of awareness of the staff about ideal phlebotomy procedures. The health care provider must be more diligent in applying scientific knowledge to reduce the errors in this pre analytical phase.

According to one study conducted by Plebani and Carraro the highest frequency of errors result from problems in the preanalytical or post-analytical phases. Hemolysis accounted for the majority of rejections in our study. There are lot of factors which leads to hemolysis of specimens like blood is forced through a fine needle, shaking the tubes vigorously, and centrifuging the specimens before clotting is complete. 4 Red top tube without any preservative should not be shaken after the sample has been collected, and plasma tubes should be gently inverted a few times so the anticoagulant mixes with the blood. In another study by Jay and colleagues, the majority of hemolyzed samples (>95%) could be attributed to in vitro processes resulting from incorrect sampling procedure or transportation errors. Hemolysis leads to the extravasation of intracellular contents into the plasma, leading to false high values of potassium and intracellular enzymes such as ALT and LDH. It also leads to delay in reporting of results due to the need for fresh specimens for processing the request.

To overcome the errors in pre analytical phase , we have developed standard operating procedures (SOPs) for the different steps involved in ideal laboratory operations and ethics. Regular training and awareness sessions of phlebotomist and specimen transporters are conducted at regular interval by quality management department. The samples are thereby transported to our laboratory from the collection center by our staff following the basic precautions that must be adhered to during transportation.

Another factor leading to rejection of blood samples in our study was insufficient blood volume. Every analytical process requires a fixed volume of serum/plasma for analysis. The main reasons behind this error are ignorance of the phlebotomists, difficult sampling as in pediatric patients, patients with chronic, debilitating diseases, and patients on chemotherapy whose thin veins are difficult to localize.

These data are comparable to those provided by other investigators, which confirm that problems directly related to specimen collection are the main cause of preanalytical errors, especially hemolyzed, clotted, insufficient, and incorrect samples. [6] [8].

With the exclusive use of vacutainers, the frequency of errors found in our study is 1.5%. It is clear from the above discussion that incorrect phlebotomy practices are the main reason behind preanalytical errors. The reason for incorrect phlebotomy practice includes lack of awareness or possibly a heavy workload. This is the reason phlebotomy has been considered a separate area of improvement for medical technicians in developed countries. Those of us in developing nations must adopt a similar approach toward phlebotomy and initiate steps for the inculcation of ideal phlebotomy practices among health care workers.

CONCLUSION:

The concept of total quality management encompasses all the steps involved in sample processing, beginning from test ordering to the final interpretation of results by the clinicians to reduce or eliminate the errors that may arise during the various steps. The promotion of ideal phlebotomy practices and sample transport procedures is a pre-requisite for the efficacy of laboratory functioning. The dependence on accurate laboratory results for diagnostics makes it mandatory for labs to ensure accountability and accuracy of results to negate incorrect diagnosis as a consequence of faulty reporting. A practice of keeping a record of the errors at all stages of analysis and then devising corrective strategies for their prevention can gradually free a laboratory from such errors. Adoption of quality control in all the phases and not merely the analytical processes and regular appraisal and audits is necessary to safeguard patient interests and deliver our services to society.

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